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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,747	03/15/2004	Roxanne Duan	PZ017P1C2	8995

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HUMAN GENOME SCIENCES INC  
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EXAMINER

MARTINELL, JAMES

ART UNIT PAPER NUMBER

1631

DATE MAILED: 08/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

## Office Action Summary

### Application No.

10/799,747

### Applicant(s)

DUAN ET AL.

### Examiner

James Martinell

### Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1631

The disclosure is objected to because of the following informalities.

- (a) In claim 1, at the end of part (d) and before part (e), the conjunction "and" should be inserted.
- (b) The instant application mentions Table 1 in many places (*e.g.*, see ¶¶ 0636-0806)). There is no Table 1 in the application. It is presumed that the table that begins at page 169 of the instant application is Table 1. If so, it should be so labeled.

Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is vague, indefinite, and incomplete.

- (a) The recitation of "which is hybridizable" is vague and indefinite because the instant application does not distinguish between hybridizable and non-hybridizable.
- (b) The recitation of "a polypeptide fragment encoded by a polynucleotide which is hybridizable to the cDNA sequence of clone HE2EB74 in ATCC Deposit No: 209225" is vague and indefinite because the limits of fragment size are not mentioned. In addition, the instant application does not disclose or define which polynucleotides may or may not be hybridizable to the cDNA sequence of clone

Art Unit: 1631

HE2EB74 in ATCC Deposit No: 209225, let alone any polypeptides that may be encoded by such hybridizable polynucleotides.

- (c) The recitation of "polypeptide domain of SEQ ID NO: 116" is vague and indefinite because the term "domain" is not defined. In addition, it is noted that SEQ ID NO: 116 is only 20 amino acids in length and the "mature" polypeptide is only 2 amino acids in length (see Table 1). With a peptide so small, it is not understood what applicants mean by the term domain. Thus, the metes and bounds of the claim are unclear.
- (d) The recitation of "polynucleotide encoding . . . a polypeptide domain encoded by a polynucleotide which is hybridizable to the cDNA sequence of clone HE2EB74 in ATCC Deposit No: 209225" is vague and indefinite because it is not clear as to what is meant by "hybridizable" (see (a) hereinabove), nor is any polypeptide that might be encoded by any polynucleotide that is hybridizable to the cDNA sequence of clone HE2EB74 in ATCC Deposit No: 209225 disclosed or delineated in any clear manner in the instant application, nor is it clear what is meant by "domain" of SEQ ID NO: 116 which is only 20 amino acids in length (see (c) hereinabove).
- (e) The recitation of "polypeptide epitope of SEQ ID NO: 116" is vague, indefinite, and incomplete because the instant application does not disclose an epitope of SEQ ID NO: 116.
- (f) The recitation of "a polynucleotide encoding . . . a polypeptide epitope encoded by a polynucleotide which is hybridizable to the cDNA sequence of clone HE2EB74 in ATCC Deposit No: 209225" is vague, indefinite, and incomplete because it is not clear as to what is meant by "hybridizable" (see (a) hereinabove), nor is any polypeptide epitope that might be encoded by any polynucleotide that is hybridizable to the cDNA sequence of clone HE2EB74 in

Art Unit: 1631

ATCC Deposit No: 209225 disclosed or delineated in any clear manner in the instant application.

- (g) The recitation of "a polynucleotide which is hybridizable to the cDNA sequence of clone HE2EB74 in ATCC Deposit No: 209225" is vague and indefinite because the instant application does not distinguish between hybridizable and non-hybridizable.
- (h) The recitation of "biological activity" is vague and indefinite because the term is not defined in the application.
- (i) The claim is vague and indefinite in view of the statement in ¶ 0030, "Some of these sequences are related to SEQ ID NO: 12 and may have been publicly available prior to conception of the present invention. Preferably, such related polynucleotides are specifically excluded from the scope of the present invention." It is most unclear as to what applicants regard as their invention because it is not known which sequences are excluded, nor is it at all clear what "preferably" means within the context of the passage.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. There is no specific, substantial, and credible utility for the claimed polynucleotides. The instant application in the Table (see page 169) discloses that SEQ ID NO: 116 is only 20 amino acids in length and that the "mature" part of the polypeptide is only 2 amino acids in length (making it not a polypeptide at all, but a dipeptide). There is no disclosed specific, substantial, and credible utility for such a small molecule in this application. Thus, there is no specific, substantial, and credible utility for the polynucleotides that encode SEQ ID NO: 116 or its mature form.

Art Unit: 1631

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The discussion in the rejection under 35 U.S.C. § 101 is incorporated here.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant application does not disclose all of the polynucleotides embraced by the claims. The instant application also does not disclose all of the polypeptides encoded by all of the polypeptides that are embraced by the claims. The instant application does not disclose polypeptides encoded by polynucleotides that are hybridizable to the cDNA sequence of clone HE2EB74 in ATCC Deposit No: 209225. In addition, the instant claims embrace genomic DNA that contains introns, yet the instant application does not provide an adequate written description of such genomic DNAs.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Matsubara et al (EP 0 679 716 A1 (November 2, 1995), an English language equivalent of WO 95/14772 (June 1, 1995)). SEQ ID NO: 6136 of Matsubara et al shares 127 nucleotides with SEQ ID NO: 12 of the instant application (compare SEQ ID NO: 12, nucleotides 763-889 to SEQ ID NO: 6136, nucleotides 14-140 and the alignment in Appendix A attached to this Office action). In addition, SEQ ID NO 1076 of Matsubara et al

Art Unit: 1631

encodes a fragment, domain, and/or an epitope of SEQ ID NO: 116 (*i.e.*, amino acids 5-11 of SEQ ID NO: 116). Thus, the claim embraces the DNAs disclosed in the reference.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719. The fax phone number for Examiner Martinell's desktop workstation is (571) 273-0719. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to [james.martinell@uspto.gov](mailto:james.martinell@uspto.gov). Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.


**PLEASE NOTE THE NEW FAX NUMBER**

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
**James Martinell, Ph.D.**  
**Primary Examiner**  
**Art Unit 1631**

7/31/04